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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,195	04/01/2004	Johan Frostegard	EPCL:012US	6441

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Steven L. Highlander
FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, TX 78701

EXAMINER	
COOK, LISA V	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,195	FROSTEGARD, JOHAN	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/720,967.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed June 20, 2006 is acknowledged (paper filed 12/5/06). In the amendments filed therein claims 1, 2, and 5-10 were modified. Claims 3-4 and 11-15 have been canceled. Currently claims 1-2 and 5-10 are pending and under consideration.

2. Objections and/or rejections of record not reiterated below have been withdrawn.

NEW GROUNDS OF REJECTIONS NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 5-7 the recitation that the reagent is useful or used in a particular assay (measures by) does not positively limit the reagent kit (product) of claim 1. More specifically, the reagent for detecting antibodies bound to phosphocholine (i.e. PAF) does not rely on the type of measurement conducted for patentability. As such the claims are vague and indefinite. If applicant intends to provide patentable distinction to the product it is suggested that the claim be clearly written to recite the limitation without introducing new matter. Appropriate correction is required.

B. Claim 8 is vague and indefinite because it is not clear if applicant intends to claim multiple phosphocholines as part of the kit. Claim 1 recites phosphocholine and claim 8 recites phosphocholine. If multiple phosphocholines are intended they should be clearly identified in the claims (maybe via 1st and 2nd language). Please clarify the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 8 is drawn to a kit comprising an *anti-Ig antibody (double antibody composition)*, however the disclosure merely teaches the utility of an alkaline phosphatase-conjugated goat anti-human IgG *(single antibody composition)*. See page 14 of the disclosure. Therefore the recitation of "anti-Ig antibody" is deemed new matter. Claim 8 also includes a non-immobilized phosphocholine in combination with a previously recited phosphocholine in claim 1. However, the disclosure does not set forth embodiments wherein multiple phosphocholines are utilized. See page 14 for example. Accordingly this is deemed new matter. Applicant is invited to show support for the claims in the instant specification in order to obviate the rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1, 5, and 8-10 are rejected under 35 U.S.C.103 (a) as being unpatentable over Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11, Collective of Authors, 1997 UDC 618.3-092:812.087.1]-078-33, submitted by applicant on 12/5/06) in view of Foster et al. (U.S. Patent #4,444,879).

Muzya et al. teach an enzyme immunoassay (EIA) to study the binding of antibodies that bind to PAF and its structural analogues. In the assay PAF (a type of phosphocholine as exemplified in the specification on page 14 lines 12-11) was placed on polystyrene microplates. The assay procedure also includes a reagent for detecting the antibodies bound to PAF (conjugates of murine monoclonal antibody with horseradish peroxidase IgM and IgG). See page 11, 2nd paragraph. The reagents are employed to measure PAF binding in blood serum test samples.

Although Muzya et al. teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations.

In other words, the reference fails to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example.

In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Muzya et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

II. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11, Collective of Authors, 1997 UDC 618.3-092:812.087.1]-078-33, submitted by applicant on 12/5/06) in view of Foster et al. (U.S. Patent #4,444,879) and further in view of Heinecke (U.S. Patent #5,731,207).

Please see Muzya et al. in view of Foster et al.

Although Muzya et al. in view of Foster et al. teach that PAF is a mediator of inflammation with a range of etiologies and the obviousness of including PAF in kit embodiments, they do not teach additional markers in combination with PAF. See page 9, last paragraph.

However, to be patentable, a novel form of an old compound must possess a new utility or a utility of a different type. In re Weijland, 587 O.G. 3, 33 CCPA 837, 154 F.2d 133, 1946 C.D. 175, 69 USPQ 86, Ex parte Hald, Paper 15 in U.S. Patent No. 2,647,145.

In other words, Muzya et al. in view of Foster et al. differ from the instant invention in not specifically teaching a kit with a reagent for assessing p-hydoxyphenyaldehyde-lysine.

However, Heinecke teaches method to evaluate p-hydoxyphenyaldehyde-lysine in serum samples. This is supported by the specification on page 3 lines 7-10. The measurement of elevated levels of p-hydoxyphenyaldehyde-lysine is taught to be useful in screening for atherosclerosis and a wide variety of disease involving activated phagocytes and/or inflammation. See column 3 for example. Both PAF and p-hydoxyphenyaldehyde-lysine were shown to be useful in inflammation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include p-hydoxyphenyaldehyde-lysine as taught by Heinecke in the PAF kit of Muzya et al. in view of Foster et al. because Heinecke taught that the measurement of elevated levels of p-hydoxyphenyaldehyde-lysine is taught to be useful in screening for atherosclerosis and a wide variety of disease involving activated phagocytes and/or inflammation. See column 3 for example. Both PAF and p-hydoxyphenyaldehyde-lysine were shown to be useful in inflammation. Further, it has been held to be within the general skill if a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

III. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11, Collective of Authors, 1997 UDC 618.3-092:812.087.1]-078-33, submitted by applicant on 12/5/06) in view of Foster et al. (U.S. Patent #4,444,879) and further in view of Barquinero et al. (Lupus, 1994, 3, 55-58).

Please see Muzya et al. in view of Foster et al.

Muzya et al. in view of Foster et al. differ from the instant invention in not specifically teaching a kit with a reagent for measuring by enzyme-linked immunoassay.

However, Barquinero et al. teach an ELISA assay to measure antibodies against platelet-activating factor (PAF) in patients with autoimmune diseases. Specifically blood sample from patients with SLE (systemic lupus crythematosus), PAPS (antiphospholip syndrome), and syphilis. PAF was shown to be significantly present in patients with syphilis. See abstract and page 55 Introduction and page 56 "ELISA technique for anti-PAF".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the reagent kit taught by Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11) in view of Foster et al. (U.S. Patent #4,444,879) in an enzyme linked immunoassay (ELISA) as taught by Barquinero et al. (Lupus, 1994, 3, 55-58) because Barquinero et al. taught that the PAF ELISA could be used to detect syphilis. See Barquinero et al. abstract and page 55 Introduction and page 56 "ELISA technique for anti-PAF".

IV. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muzya et al. (Immunologiya, 1997, Vol.6, pages 9-11, Collective of Authors, 1997 UDC 618.3-092:812.087.1]-078-33, submitted by applicant on 12/5/06) in view of Foster et al. (U.S. Patent #4,444,879) and further in view of Smal et al. (Journal of Immunological Methods, Vol.128, 1990, pages 183-188).

Please see Muzya et al. in view of Foster et al.

Muzya et al. in view of Foster et al. differ from the instant invention in not specifically teaching a kit with a reagent for measuring by radioimmunoassay.

However, Smal et al. teaches method to evaluate PAF in a specific and sensitive radioimmunoassay. In the procedure the anti-PAF antibodies showed specificity for the acetyl group at the C2 position of the PAF molecule and exhibited no significant cross-reactivity with lyso-PAF or the naturally occurring lipids. The RIA was at least as good as the platelet-based assay for PAF but the RIA was simpler to perform, had higher capacity and did not have the draw backs of the inherent variability associated with the bioassay. See abstract and pages 186-187.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to take the reagent kit taught by Muzya et al. in view of Foster et al. to measure PAF by radioimmunoassay procedures as exemplified by Smal et al. because Smal et al. taught that the RIA was at least as good as the platelet-based assay for PAF but the RIA was simpler to perform, had higher capacity and did not have the draw backs of the inherent variability associated with the bioassay. See abstract and pages 186-187.

Response to Arguments

6. Applicants arguments against the rejections of record are MOOT in light of the newly submitted claims. The rejections of record have been modified appropriately herein.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants contend that the reference of Barquinero et al. does not teach a correlation between anti-PAF antibodies and autoimmune disease. In fact, Barquinero provides a link between anti-PAF antibodies and syphilis. This argument was carefully considered but not found persuasive because there is no requirement that the prior art must suggest that the claimed product (kit) will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, 16 USPQ 2d 1897, 1904 (Fed. Cir. 1990).

Applicant's arguments against the reference of Baldo et al. are MOOT because the reference has been removed/withdrawn.

Applicant's arguments against the reference of Ostermann et al. are MOOT because the reference has been removed/withdrawn.

Applicant also contends that Muzya et al. only provide motivation to use phosphocholine as a ligand to detect antibodies to PAF, albeit in the context of gynecological disorders as opposed to CVD or syphilis.

This argument was carefully considered but not found persuasive because Muzya et al. teach PAF measurement in various disorders/diseases taught by the prior art. See Muzya et al. page 9, 3rd paragraph – page 10, 1st paragraph. Further, an obviousness rejection is proper under Dillon so long as the prior art suggests a reason or provides motivation to make the claimed invention, even where the reason or motivation is different from that discovered by Applicant. *In re Dillon*, 919 F.2d 688, 696, 16 USPQ 2d 1897, 1904 (Fed. Cir. 1990).

7. For reasons aforementioned, no claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Remsen 3C-59
571-272-0816
2/22/07

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

02/22/07